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July 30, 2021

VIA ELECTRONIC FILING

The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823;
Par Pharm., Inc. v. Amneal Pharm., C.A. No. 18-2032 (Cons.)

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Eagle in this matter. We write for both Defendants to respectfully request the Court's consideration of this letter in assessing the allegations set forth in Plaintiffs' Proposed Findings of Fact Regarding Validity and Enforceability, that certain of Defendants' "proposed findings of fact violate the Court's ruling excluding Defendants' expert Dr. Park from testifying about the impurities within lot 788435," and Defendants are trying to "back-door facts into the record that the Court ruled could not come in." (D.I. 286, ¶ 233.) Because Plaintiffs included these allegations only in their responsive submissions, Defendants had no opportunity to reply.¹ As discussed below, Plaintiffs' allegations lack merit.

Background: Defendants contend the Asserted Patents are obvious over Par's Original Vasostrict product, as evidenced by commercial lots, including lot 788435. During direct examination of Defendants' expert Dr. Park, Plaintiffs objected to him testifying about lot 788435's impurities set forth in DTX-360. (Tr. at 399:5–16.) Plaintiffs' counsel conceded DTX-360 should be admitted, but objected to Dr. Park testifying about the impurities due to insufficient disclosure in his report. (Tr. at 413:17–22.) The Court sustained the objection, (Tr. at 410:7–15), but the stability

¹ After the parties met-and-conferred, Defendants asked whether Plaintiffs would raise their objection with the Court and, if so, how. (Ex. A.) Plaintiffs responded they were "still reviewing [their] options, but ha[d] made no firm decision as to how to proceed...." (*Id.*) Plaintiffs included the objection in their *responsive* Proposed Findings of Fact without further notice.

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data in DTX-360 were admitted without objection (Ct. Exh. 1; Tr. 650:10–52:10).

Later, Defendants cross-examined Plaintiffs’ expert Dr. Kirsch on the lot 788435 data in DTX-360, without objection. Using the 12-month data, Defendants showed how that document discloses the claimed impurities and an abutting pH of the lot over time, again without any objection by Par. (Kirsch Tr. 857:188–62:8.)

In their Proposed Findings of Fact, Defendants included findings based on Dr. Kirsch’s admissions on the 12-month data for lot 788435. (D.I. 288 ¶¶ 107–14.) Defendants also included equivalent findings for the 6- and 9-month data found on the same page of DTX-360, applying the same analysis. (D.I. 288 ¶¶ 92–98, 100–106.) It is to these latter proposed findings that Plaintiffs object on the basis that they had “no supporting testimony at trial” and allegedly violate the Court’s order.

Plaintiffs’ serious allegations lack merit: Foremost, Plaintiffs misstate the Court’s Order. Although the Court sustained Plaintiffs’ objection to ***Dr. Park’s testimony*** on the basis of the disclosure in Dr. Park’s expert reports, (Tr. at 410:7–15), the Court did not rule that “***facts***” regarding the impurities data for lot 788435 “could not come in.” (*See id.*) Indeed, following the ruling, DTX-360, including the stability data for lot 788435, were admitted without objection. (Tr. 650:10–52:10.) Nor did Plaintiffs object to Defendants’ cross-examination of Dr. Kirsch on those impurities data, suggesting Plaintiffs too did not understand the Court’s Order to preclude admission of ***facts*** regarding lot 788435’s impurities. (*See* Kirsch Tr. 857:18–62:8.) To the extent Plaintiffs had any such broader objection, they waived it by not objecting during the cross-examination of Dr. Kirsch.² (*See* Tr. 305:7–19 (finding objection waived when not timely raised).)

Plaintiffs’ argument that the 6- and 9- month data had “no supporting testimony at trial,” (D.I. 286, ¶ 233), also has no basis for multiple reasons.

First, Plaintiffs are wrong that there was “no supporting testimony at trial” for the proposed findings. Defendants cross-examined Dr. Kirsch on impurities data at 12 months, and merely applied the same analysis to the 6- and 9-month data, which are presented on the same page of the exhibit. (DTX-360.25.) Particularly in the context of a timed trial, there was no need to have cross-examined Dr. Kirsch on every single cell of data, when the same analysis applies across multiple time-points.

² Any such objection would have been unavailing. Plaintiffs were on notice of Defendants’ invalidity theory, as it was set forth in the Pretrial Order. (D.I. 268, Ex. 3, ¶¶ 207–08 (asserting obviousness on the basis that “commercial lots of Original Vasostrict® were on sale and in public use at pH 3.6 ***with impurities that satisfied or bettered the limitations of the asserted claims*** of the Patents-in-Suit, ***including at least lots*** 788442, 788432, 788433, ***788435***, and 802171”).

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In any event, no supporting testimony was needed to read the impurities and pH numbers off the page for the other time points. *Cf. Wyers v. Master Lock Co.*, 616 F.3d 1231, 1242 (Fed. Cir. 2010) (“[E]xpert testimony is not required when the references and the invention are easily understandable.”).

Second, Plaintiffs conflate the Court’s ruling about Dr. Park’s testimony with the Court’s separate ruling about which exhibits could be relied on in post-trial briefing. In that regard, the Court ruled that “neither side is going to get to talk about [documents] unless there was testimony elicited about the subject matter.” (Tr. at 517:10–21.) But that ruling does not apply here. Testimony about the stability data exhibit for lot 788435 was elicited from both parties’ experts—Dr. Park spoke to the pH data, consistent with the Court’s order, and Dr. Kirsch spoke to both the pH and impurities data for that lot. (Park Tr. 414:9–14; Kirsch Tr. 857:18–61:18.)

Third, Plaintiffs themselves have proposed findings of fact based on information in admitted exhibits that are unsupported by any trial testimony. For instance, in their proposed findings of fact, Plaintiffs for the first time identify data that purportedly show the Reformulated Vasostrict product could have a longer shelf life than Original Vasostrict, even though no witness testified about those data at trial. (DTDX Ex. 2 at 235:18–22, 235:24–36:5, 297:9–98:5, 298:8–98:13; DTDX Ex. 3 at 87:15–88:5; DTDX Ex. 4 at 154:14–15, 154:17–25, 217:3–17, 217:19–21, 219:19–24, 220:20–21:7; DTDX Ex. 8 at 181:12–82:12; Kirsch Tr. at 799:20–800:4, 888:5–17.) And dozens more of Plaintiffs’ proposed findings of fact seek to draw inferences from admitted exhibits without citing any supporting testimony. (*See, e.g.*, D.I. 284 ¶¶59, 77, 79, 86, 91, 97, 102, 116; D.I. 286 ¶¶214, 228–29, 234, 237, 340–41, 346–48, 350, 363–65, 374, 382, 388–91, 394, 396, 399, 400, 402, 404, 408, 410, 437.) Under these circumstances, Plaintiffs’ complaint about two of Defendants’ Findings of Fact that *are* supported by testimony is not well taken.

For these reasons, Defendants submit that the allegations in ¶ 233 of Plaintiffs’ Proposed Findings of Fact Regarding Validity and Enforceability are unwarranted, and should be disregarded. Defendants are available to discuss the foregoing at any scheduled oral argument or otherwise at the Court’s convenience.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/7311907/45185

Enclosure

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)